REMARKS

Claims 2, 4-16, 20 and 22 are pending in the instant application.

By the present amendment, Claim 22 has been amended to include semi-solid in addition to solid pharmaceutical compositions and to contain the limitation that the physical state of the composition is a glass thermoplastic phase. Support for the amendment inserting "semi-solid" is found on page 2, lines 34-35 of the specification as originally filed, and support for the limitation that the physical state is a glass thermoplastic phase is found in claim 3 of the application as originally filed.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In the Final Rejection mailed July 9, 2001, all claims stand rejected under 35 U.S.C. 103(a) as being unpatentable over Putteman *et al.* (US 5,814,330) or EPA 0,689,844 or WO 94/12217.

Putteman *et al.* disclose compositions comprising a drug (e.g., itraconazole) and cyclodextrin which are emulsions consisting of an aqueous phase and an oil phase. (*see e.g.*, column 4, lines 6-7 of Putteman et al.). By contrast, Claim 22, as amended, claims a pharmaceutical composition comprising specified amounts of a sparingly soluble drug, a cyclodextrin, a physiologically tolerable a water-soluble acid, and a physiologically tolerable water-soluble polymer wherein the physical state of the composition is a glass thermoplastic phase. The specification on page 3, lines 13-16 explains the term "glass thermoplastic phase" as meaning that "all components are dispersed so as to form a system that is chemically and physically uniform or homogenous throughout, or consists of one phase as defined in thermodynamics." Applicant submits that the teaching of Putteman et al. of bi-phasic emulsions would not motivate one of ordinary skill in the art to make Applicant's compositions where all the ingredients form a single phase. Thus, Applicant urges that Putteman et al. do not render Applicant's claimed invention obvious.

EPA 0,689,844 discloses pharmaceutical compositions which are made by mixing a complex of vinpocetine and cyclodextrin, as the active substance, with pharmaceutically acceptable inert carriers and/or additive materials. Claim 22, as amended, claims a pharmaceutical composition comprising specified amounts of a sparingly soluble drug, a cyclodextrin, a physiologically tolerable a water-soluble acid, and a physiologically tolerable water-soluble polymer wherein the physical state of the composition is a glass thermoplastic phase and characterized in that at 5, 15 and 45 minutes after addition of a quantity of the composition containing 100 mg of drug to 600 ml of 0.1 N hydrochloric acid at 37 °C, from 7 to 25 %, from 45 to 70 % and at least 96 % of drug compound is in solution in said hydrochloric acid. Applicant submits that the teaching of EP '844 would not motivate one of ordinary skill in the art to make Applicant's claimed compositions having a specified dissolution profile and where all the ingredients form a single phase.

Thus, Applicant urges that EP '844 does not render Applicant's claimed invention obvious.

WO 94/12217 teaches a pharmaceutical composition comprising a therapeutic agent, a carboxy-containing polymer and cyclodextrin in an aqueous medium. By contrast, amended Claim 22 is drawn to a pharmaceutical composition having a physical state which is a glass thermoplastic phase. That is, a uniform or homogenous, single, semi-solid or solid phase. Applicant submits that the teaching of WO 94/12217 of a composition in a liquid phase would not motivate one of ordinary skill in the art to make Applicant's claimed compositions where all the ingredients form a single phase. Thus, Applicant submits that WO 94/12217 does not render Applicant's claimed invention obvious.

In view of the above amendment and comments, Applicants respectfully request that the Examiner withdraw the rejection of claims 22, 2, 4-16 and 20 under 35 U.S.C. 103(a) as being unpatentable over Putteman *et al.* (US 5,814,330) or EPA 0,689,844 or WO 94/12217.

A favorable disposition of the application is courteously requested.

Respectfully submitted,

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"Version with markings to show changes made."

IN THE CLAIMS

Amend Claim 22 as follows:

22. (Amended) A semi-solid or solid pharmaceutical composition comprising by weight 0.001 to 50 % of a sparingly water-soluble drug compound, 5 to 70 % of a cyclodextrin, 1 to 95 % of a physiologically tolerable water-soluble acid, and 0.05 to 35 % of a physiologically tolerable water-soluble organic polymer characterized in that at 5, 15 and 45 minutes after addition of a quantity of the composition containing 100 mg of drug to 600 ml of 0.1 N hydrochloric acid at 37 °C, from 7 to 25 %, from 45 to 70 % and at least 96 % of drug compound is in solution in said hydrochloric acid, wherein the physical state of said composition is a glass thermoplastic phase.